ject to a 503(b)(1)(B), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: Alva Laboratories, Inc., Chicago, Ill., the manufacturers of the article, appeared as claimant and filed an answer to the libel denying that the article was misbranded as alleged. Interrogatories were thereafter served upon the claimant by the Government. The claimant subsequently filed objections to answering the interrogatories. The matter came on for hearing before the court on 10–15–57, with the result that the court ordered the claimant to answer certain interrogatories and arranged for a further hearing on the matter of answering the remaining interrogatories. The claimant filed answers to some of the interrogatories on 11–14–57. Thereafter, the case remained pending to permit claimant to consider the matter of revising the labeling of the article.

On 5–4–59, the Government filed a motion to amend the libel to include the charge of 503(b)(4), as stated above, and a motion to compel further answers to the Government's interrogatories. The motion to amend the libel was granted on 6–8–59, and the motion to compel further answers to the interrogatories was granted on 8–10–59.

Thereafter, a stipulation signed by the attorneys for the claimant, the claimant's president, and the Government's attorneys was filed consenting to the entry of a decree of condemnation and acknowledging that the article was misbranded when introduced into interstate commerce in that the labeling of the article failed to bear adequate warnings for use in certain pathological conditions, namely, that the article should not be taken by persons suffering from glaucoma or increased intraocular pressure unless upon advice of a physician. Pursuant to such stipulation, the court, on 12–7–59, ordered that the article be condemned and destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6006. Various drugs. (Inj. No. 326.)

COMPLAINT FOR INJUNCTION FILED: 3–31–58, E. Dist. Wis., against Adolph Fictum, t/a Wm. Horner Co., and Wm. M. Horner Co., Green Bay, Wis., to enjoin and restrain the defendant from doing acts resulting in the misbranding of various bulk drugs and repackaged drugs, while held for sale after shipment in interstate commerce, and from introducing and delivering for introduction into interstate commerce, various bulk or repackaged drugs which were misbranded.

NATURE OF BUSINESS: The defendant was engaged in manufacturing, packing, mixing, selling, and distributing, singly and in combination the following drugs:

Wm. M. Horner's Pure Herb Health Tea or *Horner's Herb Tea* which contained senna leaves, uva ursi flowers, cascara sagrada, Spanish aniseed, licorice root, fennel seed, elder flowers, and dandelion root.

Wm. M. Horner's Ointment for Eczema and Skin Diseases which contained petrolatum, sulfur, oil of tar, creosol, phenol, and olive oil.

Wm. M. Horner's Pure Herb Laxative which contained cascara, cinnamon, cloves, nutmeg, and glycerine.

*See also No. 6005.

Wm. M. Horner's Liniment for Rheumatism and Lumbago which contained tincture of iodine and phenol.

Wm. M. Horner's Laxative for Gall Stone Treatment which contained Epsom salts and Rochelle salts.

Wm. M. Horner's Gall Stone Remedy for Inflammation of the Gall Bladder or Duct which contained olive oil, glycerine, and rhubarb.

Wm. M. Horner's Kidney Remedy which contained rhubarb, glycerine, and magnesia.

Horner's Uterine Douche Powder which contained sodium bicarbonate, alum, and sulfur.

Wm. M. Horner's Nerve Tonic for Men and Boys which contained catnip, boneset, camomile, hops, veronica, quassia chips, squill, caraway seed, cinnamon bark, glycerine, mandrake, elderberry bark and dandelion root.

Horner's Menthol Ointment which contained petrolatum, camphor, menthol crystals, liquid menthol, spirits of camphor, and peppermint.

Horner's Inhalant which contained spirits of camphor, menthol, ammonia and spirits of peppermint.

Wm. M. Horner's Dyspepsia Powder for Indigestion and Gas on Stomach which contained sodium bicarbonate, sodium chloride, cream of tartar, and pepsin.

Wm. M. Horner's High Blood Pressure or Hardening of the Arteries which contained catnip, yarrow flour, sassafras root, yellow dock root, quassia chips, garlic, camomile and peppermint.

Wm. M. Horner's Body Builder which contained gentian root, yellow dock root, sassafras root, camomile, juniper, dandelion root, wine, tincture of iodine, cascara and glycerine.

Wm. M. Horner's Blood and Stomach Tonic which contained petrolatum, cascara, cinnamon, cloves, and nutmeg.

Wm. M. Horner's Nerve Remedy for Female Disorders which contained catnip, boneset, camomile, hops, veronica, quassia chips, squill, caraway seed, cinnamon bark and glycerine.

The above-mentioned ingredients of the drugs were received in bulk from interstate sources.

ALLEGED VIOLATION: The defendant was causing labeling to accompany the above-named drugs, and the bulk drugs intended for use as ingredients thereof, which act was done while the drugs were held for sale by the defendant after shipment in interstate commerce and resulted in the drugs being misbranded as hereinafter described.

The defendant was also causing *Horner's Pure Herb Health Tea* or *Horner's Herb Tea* and *Wm. M. Horner's Ointment for Eczema and Skin Diseases* to be introduced and delivered for introduction into interstate commerce in a misbranded condition as hereinafter described.

CHARGE: The complaint alleged that the drugs were misbranded as follows:

(a) that the *Wm. M. Horner's Pure Herb Health Tea* or *Horner's Herb Tea* were misbranded when shipped in interstate commerce and, that while held for sale by the defendant, such drugs together with the bulk drugs for use as ingredients thereof were misbranded in the following respects:

502(a)—the labeling of the drugs contained false and misleading representations that the articles were adequate and effective in the treatment of constipation, bowel trouble, stomach, kidney, and bladder trouble, pimples, gas, indigestion, and tired feeling; the labeling falsely designated

the articles as a "Tea"; the labeling statements "Nature has given us Roots and Herbs for many ailments yet how sadly does the present generation neglect them" and "Why Not Use Herbs and Roots when nature has produced them for many ills of mankind" were false and misleading since such statements represented and suggested that the articles were adequate and effective in the treatment of all the ailments of mankind, whereas, the article was not adequate and effective in the treatment of all the ailments of mankind; and

502(f)—the labeling of the articles (1) failed to bear adequate directions for use for the purposes for which they were intended; and (2) such adequate warnings against use in those pathological conditions, or by children, where their use may be dangerous to health, or against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users since the articles were essentially laxatives, and their labeling failed to warn that the article should not be taken when abdominal pain (stomach ache, cramps, colic), nausea, vomiting (stomach sickness), or other symptoms of appendicitis were present; and their labeling also failed to warn against frequent or continued use since such use may result in dependence on laxatives to move the bowels;

(b) that the Ointment for Eczema and Skin Diseases was misbranded when shipped in interstate commerce, and, that while held for sale by the defendant, such drug together with the bulk drugs for use as ingredients thereof were misbranded in the following respect:

502(a)—in that their labeling was false and misleading since the articles were not effective in the treatment of eczema and all skin diseases;

(c) that the Pure Herb Laxative, Liniment for Rheumatism and Lumbago, and Laxative for Gall Stone Treatment and the bulk drugs used as ingredients thereof were, while held for sale by the defendant, misbranded in the following respects:

502(a)—the labeling of the articles contained false and misleading representations that the Pure Herb Laxative was an adequate and effective treatment for chronic constipation, biliousness, headaches, bad breath, and excessive gas in the stomach; that the Liniment for Rheumatism and Lumbago was an adequate and effective treatment for rheumatism, lumbago, and external inflammation, swelling and pain; and that the Laxative for Gall Stone Treatment was an adequate and effective treatment for gall stones;

502(f)(1)—the labeling of all three articles failed to bear adequate directions for use for the purposes for which they were intended;

502(f)(2)—the labeling of the articles failed to bear warnings against unsafe dosage and duration of administration and application since the articles "Herb Laxative" and "Laxative for Gall Stone Treatment" were essentially laxatives and their labeling failed to warn that the articles should not be taken when symptoms of appendicitis are present and that frequent or continued use of the articles may result in dependence on laxatives; and since the article "Liniment for Rheumatism and Lumbago" was a counter-irritant containing phenol (carbolic acid) and its labeling failed to warn that use of the article may cause excessive irritation, that the user should avoid getting it into the eyes or on mucous membranes, that when applied to the fingers and toes a bandage should not

be used, and that the article should not be applied to large areas of the body;

(d) that the remainder of the above-named drugs and the bulk drugs used as ingredients thereof were misbranded, while held for sale by the defendant, in the following respects:

502(a)—the labeling of the articles contained false and misleading representations that the Gall Stone Remedy for Inflammation of the Gall Bladder or Duct was an adequate and effective treatment for gallstones and gallstone colic; that the Kidney Remedy was an adequate and effective treatment for kidney stones, bed wetting, and weakened kidneys; that the Uterine Douche Powder was an adequate and effective treatment for irrigation of the vaginal tract and as a uterine douche; that the Nerve Tonic for Men and Boys was an adequate and effective treatment for hysterics, nervous irritability, inducing natural sleep, calming the nerves in general, malfunction of the digestive tract or kidneys, mental strain, sickness, impaired nutrition. nervousness, tired and worn-out feeling, loss of ambition, facial pallor, tiring easily at work, headaches, dizziness, sleeplessness, and traveling aches in various parts of the body; that the Menthol Ointment was an adequate and effective treatment for muscular rheumatism, nasal catarrh, head cold, sinus, cuts, bruises, chapped hands and insect bites; that the Inhalant was an adequate and effective treatment for sinus, catarrh, asthma and hay fever; that the Dyspepsia Powder for Indigestion and Gas on Stomach was recommended as an adequate and effective treatment for indigestion, gas on stomach, gastritis, to supplement and restore the gastric juice, sick headache, dizziness, sour stomach, heartburn, nausea, nervousness, bloating of the stomach and bowels, dyspepsia, inability to eat certain foods, and constipation; that the article for High Blood Pressure or Hardening of the Arteries was an adequate and effective treatment for high blood pressure, hardening of the arteries, over-eating, over-work, worry, headaches, dizziness, pain around the heart, obscure nervous disorders, angina pectoris and breaking-down of the functioning of the kidneys; that the Body Builder was an adequate and effective treatment for weak and run-down conditions of men and women, to excite secretions, to relax constrictions, to soothe nerves, no appetite, for the removal of morbid materials of the alimentary canal, to tone up the system, increase nutrition, restore a healthy condition, rheumatism, headaches, no pep, sleeplessness, drowsiness, numbness of arms and hands, loss in weight, simple anemia and loss of color and for general weakness of the body; that the Blood and Stomach Tonic was an adequate and effective treatment for chronic blood and stomach ailments, elimination of waste materials, purification of the blood, chronic constipation, weak or nervous stomach, ulcers, and impure blood; that the Nerve Remedy For Female Disorders was an adequate and effective treatment for overcoming present weaknesses, stabilizing the changing of the female organism from puberty through menopause, headaches, dizziness, nervousness, sleeplessness, loss of appetite, pallor of the face, agonizing pain and complete nervous exhaustion; and

502(f)(1)—in that their labeling failed to bear adequate directions for use for the purposes for which they were intended;

It was alleged also that the defendant had been warned by the Food and

Drug Administration that his drugs were violative of the Act through establishment inspections, by letter, by a hearing and through two seizures of the article of drug designated as "Herb Tea" which seizures were terminated by default; and, that despite such warnings, defendant continued to violate the Act as specified above.

It was alleged further that if defendant was forced by an injunction to refrain from using the present labeling on the articles of drugs distributed by him, the said defendant would not discontinue such distribution but would, unless enjoined, continue to distribute in interstate commerce, and while held for sale after shipment in interstate commerce, such articles of drugs without labeling, or through collateral media outside of labeling. In such case, the articles of drugs would be misbranded within the meaning of Section 502(f)(1) of the Act in that their labeling would fail to bear adequate directions for use for the purposes for which they were intended.

DISPOSITION: Following a conference prior to a hearing on the motion for preliminary injunction on 5–26–58, the court ordered (1) that the defendant submit proposed labels and quantitative formula to the Government by mail not later than 6–2–58, and (2) that the Government thereafter comment on the proposed labels and proceed with its motion for preliminary injunction if the labels were objectionable. Subsequently, on 6–29–59, the defendant having relabeled the products, and the United States Attorney having agreed, the case was ordered dismissed by the court.

6007. Pre-Creatine (betaine anhydrous). (F.D.C. No. 43129. S. Nos. 38–991/2 P, 38–993/7 P.)

QUANTITY: 1 drum, containing 15 lbs. Pre-Creatine capsules, 108 8-oz. btls. of Pre-Creatine granules, 58 100-capsule btls. and 21 50-capsule btls. of *Pre-Creatine*, at Palo Alto, Calif.

SHIPPED: During 1958, the Polychemical Laboratories, Inc., shipped from New York, N.Y., to a manufacturer at San Jose, Calif., quantities of betaine anhydrous.

LABEL IN PART: (Drum) "Pre-Creatine Caps."; (btl.) "Granules Pre-Creatine, Lemon–Orange Flavor * * * Effervescent Recomended Dosage 1 Tablespoonful * * * Each Tablespoonful Contains Approx: betaine anhydrous 2 grams glycocyamine 0.5 grams," "Capsules Pre-Creatine * * * Recommended Dosage 2 capsules t.i.d. Each Capsule Contains betaine anhydrous 400 mg. glycocyamine 100 mg."

RESULTS OF INVESTIGATION: The California manufacturer used the betaine anhydrous in the manufacture of the *Pre-Creatine* and shipped in bulk the drug so manufactured to a dealer at Palo Alto, Calif. The drugs in the bottles labeled as described above were repacked by the dealer from the bulk stock shipped to him from the California manufacturer.

LIBELED: 5–6–59, N. Dist. Calif.

CHARGE: 502(f)(1)—the labeling of the betaine anhydrous, when shipped in interstate commerce, failed to bear adequate directions for use and such article was not entitled to exemption from the requirement that its labeling bear adequate directions.

DISPOSITION: 9–30–59. Default—destruction.